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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,582	02/17/2004	Jane P. Bearinger	IL-11213	2811

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Eddie E. Scott
Assistant Laboratory Counsel
Lawrence Livermore National Laboratory
P.O. Box 808, L-703
Livermore, CA 94551

EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,582	BEARINGER ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-21,23-32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-21, 23-32, 34, 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment received on 12/13/2006. Currently claims 1, 4-21, 23-32, 34, and 35 are pending. Claims 2, 3, 22, and 33 have been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-11, 16-24, 26, 28, 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Linden et al. (US 5,634,936).

Linden discloses:

Claim 1: Apparatus for closure of a physical anomaly having a lumen, the apparatus comprising a closure body, said closure body made of a shape memory polymer (SMP), said shape memory polymer (SMP) being formed into a primary shape (Item 12), compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, wherein said shape memory polymer (SMP) provides said closure body with said reduced secondary stable shape configured for positioning said closure body within said lumen, and said primary shape configured to close said anomaly (Fig 4b).

Claim 4: said shape memory polymer (SMP) comprises a shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} (Col 4 Line 7, how the segments are formed are considered to be product-by-process claims).

Claim 6: said closure body comprises a shape memory material having a substantially barbell shape (Fig 4b).

Claim 8: said closure body comprises a shape memory material having a substantially double truncated cone shape (Col 2 Line 65, the Examiner considers "dumbbell shape" as stated in the reference to include the double truncated cone shape; furthermore, the Examiner considers the barbell shape as described in claim 6 to be substantially equivalent to the double truncated cone shape of claim 8).

Claim 9: said closure body comprises a shape memory material having a substantially flowing fluid shape (Fig 3 Item 12).

Claim 10: said closure body is biodegradable (Abstract).

Claim 11: a delivery catheter (Col 4 Line 66).

Claim 16: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof (the Examiner considers this to be intended use and gives it no patentable weight).

Claim 17: an actuator configured to transition the closure body from the reduced secondary shape to the primary shape (Fig 4b).

Claim 18: the actuator is chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof (Fig 4b Item 20).

Claim 19: A method of closing a physical anomaly having a passage, the method comprising: providing a closure body made of a shape memory polymer (SMP) (Item 12), said shape memory polymer (SMP) capable of being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape (Fig 4b), positioning said closure body made of said shape memory polymer (SMP) in the passage of the physical anomaly when said closure body is disposed in said reduced secondary stable shape, and transitioning said closure body made of a shape memory polymer (SMP) to said primary shape within the passage, thereby closing said anomaly (Fig 4b).

Claim 20: transitioning the closure body further comprises transitioning the closure body with an actuator (Fig 4b Item 20).

Claim 21: transitioning the closure body, with an actuator further comprises transitioning the closure body with an actuator chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof (Fig 4b Item 20).

Claim 23: said step of positioning a closure body further comprises positioning a shape memory polymer foam body having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft

segment is formed at a temperature below T_{trans} (Col 4 Line 7, how the segments are formed are considered to be product-by-process claims).

Claim 24: positioning a closure body in the passage of the physical anomaly when said closure body is disposed in a reduced secondary shape further comprises positioning the closure body with a delivery catheter (Col 4 Line 66).

Claim 26: transitioning said closure body comprises transitioning the closure body with a polymer body with a generally flowing fluid shape (Fig 3 Item 12).

Claim 28: positioning a closure body in the passage of the physical anomaly when said closure body is disposed in a reduced secondary shape further comprises positioning the closure body with a polymer body with a generally barbell shape (Fig 4b).

Claim 30: positioning a polymer body in the passage of the physical anomaly when said polymer body is disposed in a reduced secondary shape further comprises positioning the closure body with a polymer body with a generally double truncated cone shape (Col 2 Line 65, the Examiner considers "dumbbell shape" as stated in the reference to include the double truncated cone shape; furthermore, the Examiner considers the barbell shape as described in claim 6 to be substantially equivalent to the double truncated cone shape of claim 8).

Claim 31: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof (Abstract).

Claim 32: A system for the closure of a physical anomaly having a passage, the system comprising: a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP), said shape memory polymer (SMP) being formed into a

primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, said shape memory polymer (SMP) reduced secondary stable shape configured for positioning the body in the passage of the physical anomaly (Fig 4b Item 12'), means for positioning said closure body in the passage of the physical anomaly when said closure body is in said reduced secondary stable shape (Fig 4b); and means for transitioning said closure body to said primary shape for closing said anomaly (Fig 4b).

Claim 34: said closure body comprises a shape memory polymer foam body with a secondary shape for being positioned in the passage of the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam body having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} (Fig 4b and Col 4 Line 7, how the segments are formed are considered to be product-by-process claims).

Claim 35: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof (the Examiner considers this to be intended use and gives it no patentable weight).

Claims 1, 19, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamiya et al. (US 5,192,301).

Kamiya discloses:

Claim 1: Apparatus for closure of a physical anomaly having a lumen, the apparatus comprising a closure body (21) , said closure body made of a shape memory polymer (SMP) (Col 1 Line 44), said shape memory polymer (SMP) being formed into a primary shape (Item 12), compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, wherein said shape memory polymer (SMP) provides said closure body with said reduced secondary stable shape configured for positioning said closure body within said lumen, and said primary shape configured to close said anomaly (Col 3 Lines 16-25).

Claim 19: A method of closing a physical anomaly having a passage, the method comprising: providing a closure body made of a shape memory polymer (SMP) (Item 21), said shape memory polymer (SMP) capable of being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, positioning said closure body made of said shape memory polymer (SMP) in the passage of the physical anomaly when said closure body is disposed in said reduced secondary stable shape, and transitioning said closure body made of a shape memory polymer (SMP) to said primary shape within the passage, thereby closing said anomaly (Col 3 Lines 16-25).

Claim 32: A system for the closure of a physical anomaly having a passage, the system comprising: a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) (21), said shape memory polymer (SMP) being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, said shape memory polymer (SMP)

reduced secondary stable shape configured for positioning the body in the passage of the physical anomaly (Col 3 Lines 16-25), means for positioning said closure body in the passage of the physical anomaly when said closure body is in said reduced secondary stable shape (Col 3 Lines 16-25); and means for transitioning said closure body to said primary shape for closing said anomaly (Col 3 Lines 16-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Michlitsch (US 2006/0155330).

Linden discloses the invention substantially as claimed as stated above.

Linden does not disclose a plunger actuator; a backbleed tube; a restraint tube.

Michlitsch teaches a plunger actuator (Fig 4A Item 20); a backbleed tube (Fig 4A Item 30) and a restraint tube (Fig 5B Item 74). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Michlitsch's plunger, backbleed tube, and restraint

tube. Such modifications would allow the user to determine when the device has reached the closure site. The restraint tube is used to keep the closure plug in its proper location prior to delivery. The plunger is used to push the closure plug out of the delivery device.

Claims 5, 7, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Li (US 5,571,181).

Linden discloses the invention substantially as claimed as stated above. Linden further discloses the closure plug being capable of being shaped as needed (Col 2 Line 65), but Linden does not explicitly disclose a band shape or a spherical shape.

Li teaches a plug in a spherical shape and a band shape (Col 9 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Li's spherical and band shape. Such modifications would provide a plug that fits the defect.

Claims 1, 4, 6, 8-11, 16-21, 23, 24, 26, 28, 30-32, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Langer et al. (US 6,388,043).

The Examiner considers the Linden reference to disclose the shape memory polymer as claimed. However, because the Applicant has traversed this rejection, the Examiner is providing an alternative rejection. Langer teaches a shape memory polymer foam that can be used in medical applications (Col 3 Line 1-20). Langer further discloses that

shape memory polymers have hard and soft segments formed at given temperatures (Col 3 Lines 1-20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's article to include Langer's shape memory polymer foam. Such a modification would provide a material that can be inserted into the body in one shape and then return to a predetermined shape upon heating.

Claims 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) and Langer et al. (US 6,388,043) in view of Michlitsch (US 2006/0155330).

Linden and Langer disclose the invention substantially as claimed as stated above. Linden does not disclose a plunger actuator; a backbleed tube; a restraint tube. Michlitsch teaches a plunger actuator (Fig 4A Item 20); a backbleed tube (Fig 4A Item 30) and a restraint tube (Fig 5B Item 74). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Michlitsch's plunger, backbleed tube, and restraint tube. Such modifications would allow the user to determine when the device has reached the closure site. The restraint tube is used to keep the closure plug in its proper location prior to delivery. The plunger is used to push the closure plug out of the delivery device.

Claims 5, 7, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) and Langer et al. (US 6,388,043) in view of Li (US 5,571,181).

Linden and Langer disclose the invention substantially as claimed as stated above. Linden further discloses the closure plug being capable of being shaped as needed (Col 2 Line 65), but Linden does not explicitly disclose a band shape or a spherical shape. Li teaches a plug in a spherical shape and a band shape (Col 9 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Li's spherical and band shape. Such modifications would provide a plug that fits the defect.

Response to Arguments

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection. Because of the amendments to the independent claims, a new rejection has been given.

The Applicant has argued that the Linden reference does not disclose the shape memory polymer of the amended claims. The "hardenable polymeric materials" of the reference are considered to be different from the "shape memory polymer (SMP) being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape." The Examiner disagrees. The claim does not exclude the polymer from being hardenable. The reference discloses that the device is compressed to allow the device to be inserted into a tube.

The device is then delivered to the defect site and removed from the tube. Upon removal from the tube, the device returns to its preformed shape (Col 5 Line 39-50 and Col 7 Line 8). Once the device has been delivered, an agent may be added to harden the device. This description is substantially similar to the Applicant's description. The structure of the reference clearly reads on the structure of the Applicant's claimed invention. Therefore, the Examiner considers the rejection above to be appropriate and proper.

The Kamiya reference clearly discloses a shape memory polymer substantially similar to the Applicant's claimed invention as stated above.

The amendments to claims 4, 23, and 34 include product-by-process limitations. This does not require the prior art to disclose the particular process. Only the structural limitations need to be present.

The Langer reference discloses a foam material that is substantially similar to the Applicant's. The Examiner considers it within the purview of one having ordinary skill in the art to use such a foam material for closure of a physical anomaly as described in Linden. The Applicant's foam material does not appear to be a novel material, at least not as claimed. Any possible novelty appears to be in the use of the foam, not in the foam's structure. The Examiner has found no novelty in the foam's use because it is known in the art to use foam materials for closing physical anomalies as stated above. Therefore, the currently amended claims do not overcome the prior art.

The Applicant's arguments directed to the 103 obviousness rejections are based solely on the alleged deficiencies in the Linden reference. The Examiner has addressed the argument above and considers this sufficient for the 103 arguments.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hayashi et al. (US 5,049,591) discloses a shape memory polymer substantially similar to the Applicant's claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
2/12/07.